REMARKS

This Amendment is submitted in response to the January 10, 2007 Office Action issued by the United States Patent and Trademark Office. Claims 14-17 were pending. Applicant has hereinabove cancelled without prejudice claims 14-17 and has added new claims 18-21. Applicant has also amended the Abstract. No new matter has been added by this Amendment. Support for new claims 18-21 can be found throughout the specification. Accordingly, applicant respectfully requests entry of this Amendment.

Objection to the Specification

In the January 10, 2007 Office Action, the Examiner objected to the Abstract of the specification for using the term "novel" in describing the invention. Applicant has hereinabove deleted the term "novel" from the Abstract. Accordingly, the objection to the specification is now moot.

Non-Statutory Double Patenting Rejection

In the January 10, 2007 Office Action, the Examiner rejected claims 14-17 based on the judicially created doctrine of non-statutory double patenting as being allegedly unpatentable over claims 1, 25 and 26 of U.S. Patent No. 6,632,180. Applicant respectfully traverses this rejection.

Without conceding the appropriateness of the Examiner's rejection and to expedite prosecution of the instant application, applicant concurrently submits an appropriate terminal disclaimer. Accordingly, applicant respectfully submits that the non-statutory double patenting rejection is now moot.

Rejection of Claims Under 35 U.S.C. § 103(a)

In the January 10, 2007 Office Action, the Examiner rejected claims under 35 U.S.C. § 103(a) citing a 1978 reference by F. Gilbert McMahon ("McMahon"). The Examiner also rejected the claims under 35 U.S.C. § 103(a) by combining McMahon with a 1998 article by John H. Laragh ("Laragh"). Applicant respectfully traverses these rejections.

Without conceding the bases for the Examiner's rejections, applicant has hereinabove cancelled without prejudice claims 14-17 and has submitted new claims 18-21. New claims 18 and 19 are the only currently pending independent claims and recite, respectively:

> A method of treating a hypertensive subject having a normal to above normal PRA level comprising:
>
> A. administering to the subject or instructing the subject to take a low dose of an R drug;
>
> B. after step A, measuring the subject's BP and if the subject's BP is not controlled, administering to the subject or instructing the subject to take an increased dose of the R drug;
>
> C. after step B, measuring the subject's BP and if the subject's BP is not controlled, administering to the subject or instructing the subject to take, instead of the R drug, a low dose of a V drug; and
>
> D. after step C, measuring the subject's BP and if the subject's BP is not controlled, administering to the subject or instructing the subject to take an increased dose of the V drug.
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> * * *
>
> A method of treating a hypertensive subject having a normal to below normal PRA level comprising:

A. administering to the subject or instructing the subject to take a low dose of an V drug;

B. after step A, measuring the subject's BP and if the subject's BP is not controlled, administering to the subject or instructing the subject to take an increased dose of the V drug;

C. after step B, measuring the subject's BP and if the subject's BP is not controlled, administering to the subject or instructing the subject to take, instead of the V drug, a low dose of a R drug; and

D. after step C, measuring the subject's BP and if the subject's BP is not controlled, administering to the subject or instructing the subject to take an increased dose of the R drug.

In order to establish a *prima facie* case of obviousness, the Examiner must show each of the following:

(1) that the prior art reference or references either teach or suggest all of the claim limitations;

(2) that there is some suggestion or motivation to modify the reference or combine the teachings of references; and

(3) that there is a reasonable expectation of success in such modification or combination.

(See In re Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); MPEP §§ 2142 and 2143.)

Applicant respectfully submits that a *prima facie* case of obviousness cannot be established based on McMahon alone or in combination with Laragh, since none of these three requirements, much less all of them, can be met as applied to the presently pending claims. More specifically, the cited references taken together or alone, do not disclose, teach or suggest

applicant's presently claimed invention which is directed to utilizing PRA measurements to guide a specific course of treatment for hypertension; there is not motivation to modify or combine the cited references to arrive at the claimed invention; and, therefore, there can be no reasonable expectation of success. Applicant specifically addresses below the references cited by the Examiner.

The McMahon Reference

The Examiner maintained that McMahon teaches that some clinics routinely test patients for renin activity, that high renin patients can be administered an R drug alone, and that low renin patients can be administered a V drug alone. The Examiner further stated that McMahon also teaches that when one drug does not appear to be working, a second drug of a second type can be added to the treatment regimen and that the drugs can be titrated to effect.

Applicant notes that while McMahon suggests that a few clinics may have classified subjects based on renin levels, the reference does not suggest that those clinics used renin measurements to direct a course of treatment consistent with the new claims. Moreover, McMahon clearly states that the Joint National Committee ("JNC") and the vast majority of physicians usually begin treatment of hypertensive out-patients with a diuretic without first assessing PRA levels. As pointed out by the Examiner, McMahon urges his readers to "Treat the hypertension!" -- "Don't treat the renin level!" (*See* McMahon p. 4.) In this respect, McMahon teaches away from the presently claimed invention since McMahon does not recognize that a course of treatment should begin with an initial measurement of a subject's PRA level which is then used to guide the specific treatment that follows.

McMahon also teaches away from the present invention by urging his readers to follow the JNC recommendations that "[w]hen a patient fails on one Step 2 drug, another Step 2

drug should ordinarily be tried before proceeding to Step 3." As shown in McMahon's Table 1, Step 2 drugs include V drugs (e.g., prazosin) AND R drugs (e.g., clonidine) (*See* McMahon p. 5.) The present invention does not follow the above-described JNC recommendation. Rather, the present invention directs treatment based on an initial PRA measurement, followed by administration of a V or R drug based on that PRA measurement, followed by upward titration of the V or R drug if hypertension persists, followed by a switch from V to R or R to V (as the case may be) if hypertension still persists, followed by upward titration of the recently introduced V or R drug if hypertension continues to persist. McMahon does not suggest such a course of treatment.

The Laragh Reference

The Examiner also rejected the claims as obvious over McMahon in view of Laragh. The Examiner took the position that Laragh discloses a threshold level of 0.65 ng/ml/hr and thus cures this deficiency in McMahon. A careful review of Laragh, however, confirms that the reference does not disclose the specific course of treatment recited in the presently pending claims.

More specifically, the Laragh reference does not disclose, teach or suggest a course of treatment based on an initial PRA measurement, followed by administration of a V or R drug based on that PRA measurement, followed by upward titration of the V or R drug if hypertension persists, followed by a switch from V to R or R to V (as the case may be) if hypertension still persists, followed by upward titration of the recently introduced V or R drug if hypertension continues to persist.

For the reasons given above, applicant maintains that a *prima facie* case of obviousness cannot be made since (1) the McMahon and Laragh references do not teach or

suggest all of the claim limitations; (2) there is no suggestion or motivation to modify the references or combine the teachings of references to arrive at the claimed invention; and (3) therefore, there can be no reasonable expectation of success to arrive at the claimed invention. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

Conclusion

In view of the foregoing, applicant respectfully requests that the Examiner reconsider and withdraw the objections and rejections raised in the January 10, 2007 Office Action and allow the presently pending claims, namely claims 18-21.

No fee is believed to be necessary in connection with the filing of this Amendment. If any fee is necessary, however, applicant hereby authorizes such fee to be charged to Deposit Account No. 50-0540.

If a telephone interview would be of assistance in advancing prosecution of this application, applicant's undersigned attorney encourages the Examiner to telephone him at the number provided below.

Respectfully submitted,

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